UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,922	03/30/2005	Sarah S. Bacus	PU4995USw	6645

23347 7590 06/06/2007

GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B475
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,922	BACUS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-26 are pending in the application and are currently under prosecution.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1

Group 1, claims 1-in-part, 2-4, 6-in-part, 7, 8 are drawn to a method of assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, administering an effective amount of EGFR inhibitor.

Group 2, claims 1-in-part, 2-4, 6-in-part, 7, 8 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, administering an effective amount of an erbB2 inhibitor.

Group 3, claims 1-in-part, 2-4, 6-11 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, administering an effective amount of a dual EGFR/erbB2 inhibitor.

Group 4, claims 1-in-part, 2-5, 6-in-part, 7, 8 are drawn to a method of assessing whether a subject who presents with an EGFR-expressing solid

tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, administering an effective amount of EGFR inhibitor.

Group 5, claims 1-in-part, 2-5, 6-in-part, 7, 8 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, administering an effective amount of an erbB2 inhibitor.

Group 6, claims 1-in-part, 2-11 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, administering an effective amount of a dual EGFR/erbB2 inhibitor.

Group 7, claims 1-in-part, 2-4, 6-in-part, 7, 8, 12 are drawn to a method of assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of pAKT in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of EGFR inhibitor.

Group 8, claims 1-in-part, 2-4, 6-in-part, 7, 8, 12 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the

level of pAKT in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of an erbB2 inhibitor.

Group 9, claims 1-in-part, 2-4, 6-12 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of pAKT in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of a dual EGFR/erbB2 inhibitor.

Group 10, claims 1-in-part, 2-5 6-in-part, 7, 8, 12 are drawn to a method of assessing whether a subject who presents with an EGFR-expressing solid tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of pAKT in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of EGFR inhibitor.

Group 11, claims 1-in-part, 2-5, 6-in-part, 7, 8, 12 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of pAKT in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of an erbB2 inhibitor.

Group 12, claims 1-in-part, 2-12 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which

also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of pAKT in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of a dual EGFR/erbB2 inhibitor.

Group 13, claims 1-in-part, 2-4, 6-in-part, 7, 8, 13 are drawn to a method of assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of EGFR inhibitor.

Group 14, claims 1-in-part, 2-4, 6-in-part, 7, 8, 13 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of an erbB2 inhibitor.

Group 15, claims 1-in-part, 2-4, 6-11, 13 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of

treatment, administering an effective amount of a dual EGFR/erbB2 inhibitor.

Group 16, claims 1-in-part, 2-5 6-in-part, 7, 8, 13 are drawn to a method of assessing whether a subject who presents with an EGFR-expressing solid tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of EGFR inhibitor.

Group 17, claims 1-in-part, 2-5, 6-in-part, 7, 8, 13 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of an erbB2 inhibitor.

Group 18, claims 1-in-part, 2-11, 13 are drawn to a method assessing whether a subject who presents with an EGFR-expressing solid tumor, which also expresses erbB2, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of treatment, administering an effective amount of a dual EGFR/erbB2 inhibitor.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1, claims 1-in-part, 2-4, 6-in-part, 7, 8 is drawn to a method of assessing whether a subject who presents with an EGFR-expressing solid tumor, which does not express erbB2 as contemplated in the specification, is likely to exhibit a favorable clinical response to treatment comprising determining the pre-treatment level of pERK in said tumor, administering an effective amount of EGFR inhibitor. The Group therefore forms a single general inventive concept.

Groups 2-18 are drawn to methods different than the method of the first Group.

4. Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number

is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898.. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Ungar, PhD
Primary Patent Examiner
May 30, 2007